

Protocol Submission Worksheet v2.0

Please print or type. Complete all relevant sections. Attach to protocol and submit to the above address.

SECTION 1: GENERAL INFORMATION Required for ALL protocols

1.A Overview of Protocol Information:

Organization (local) Protocol No.: _____

Protocol Title: _____

Name of Lead Organization: _____ NCI Institution Code¹: _____
(e.g., Group, Consortium, Institution)

Principal Investigator (PI) Name: _____ NCI Investigator No.²: _____

PI Phone No.: () _____ PI Fax No.: () _____ PI E-mail Address: _____

Is this a Multi-Center (Non-Cooperative Group) Protocol? ☐yes ☐no If yes, refer to the Multi-Center Guidelines, Section 7.3.2 in Investigator Handbook, at <http://ctep.info.nih.gov/handbook/handbook/default.htm> for further instructions.

Study Phase (circle one): 1, 1/2, 2, 3, pilot, Other

Have you submitted a Letter of Intent or Concept for this protocol? ☐yes ☐no If yes, provide the **NCI LOI/Concept No.**: _____

Is this protocol part of an NIH Grant? ☐yes ☐no ☐pending If yes, provide the **Grant No.**: _____

Is this protocol part of an NIH Cooperative Agreement (CA) or Contract? ☐yes ☐no ☐pending If yes, provide the **CA or Contract No.**: _____
(Examples: Grant and Cooperative Agreement Number – U01 CA 12345;
Contract Number – N01 CM 12345)

Are you receiving support from non-NCI sources (i.e., industry, ACS) for this study? ☐yes ☐no If yes, specify the source: _____

Will inpatient therapy be required for the investigational portion of this study? ☐yes ☐no
(Inpatient therapy - >24hrs in a medical facility for investigational intervention. Answer 'No' if inpatient therapy is only required as part of the standard therapy portion of the study.)

Projected Start Date of Study: _____ NCI Sponsor (i.e., provides IND/Funding) (circle one) CTEP, DCP, Other (Specify): _____

Specify the Study Type (select ALL that apply):

- ☐ Treatment* (An intervention to reduce the morbidity and mortality of cancer. The focus of the intervention is the primary cancer diagnosis.)
- ☐ Cancer Control (An intervention to reduce the morbidity and complications of cancer or its treatment focusing on supportive care, not the primary cancer diagnosis.)
- ☐ Prevention, please specify: ☐ primary malignancy ☐ secondary malignancy (An intervention to reduce the risk of developing cancer.)
- | | | | |
|---|---|--|---|
| <input type="checkbox"/> Age-Related | <input type="checkbox"/> Epidemiology | <input type="checkbox"/> PET Scanning | <input type="checkbox"/> Screening |
| <input type="checkbox"/> Cell Kinetics | <input type="checkbox"/> Flow Cytometry | <input type="checkbox"/> Pharmacologic Assays | <input type="checkbox"/> Statistical Methodology |
| <input type="checkbox"/> Cytogenetics | <input type="checkbox"/> Immunologic Assay | <input type="checkbox"/> Photodynamics | <input type="checkbox"/> Supportive Care/Symptom Management |
| <input type="checkbox"/> Diagnostic Imaging | <input type="checkbox"/> Laboratory Correlation | <input type="checkbox"/> Psycho-Social | <input type="checkbox"/> Tissue Banking |
| <input type="checkbox"/> Drug Sensitivity | <input type="checkbox"/> Marker Study | <input type="checkbox"/> Quality of Life | <input type="checkbox"/> Tissue Sampling |
| <input type="checkbox"/> Early Detection | <input type="checkbox"/> Molecular Biology | <input type="checkbox"/> Race Related | <input type="checkbox"/> Tumor Marker |
| <input type="checkbox"/> Economic | <input type="checkbox"/> Pathology | <input type="checkbox"/> Radiation Immunotherapy | <input type="checkbox"/> Other (Specify): _____ |

¹ See <http://ctep.info.nih.gov/codesand.htm> for a complete list of Organization (Group, Consortium and Institution), IND and NSC Numbers and Disease Names and Codes.

² Contact the Pharmaceutical Management Branch (PMB) at (301) 496-5725 to obtain NCI Investigator Numbers.

³ Section 3, "Subgroup" and Section 4, "Treatment Assignment" originally included in the 3/3/1999 Protocol Submission Worksheet were deleted from this form.

1.B Specify Agents to be used to Address the Objectives of Study:

| Agent Name | Request for NCI-Supplied? (Y/N) | Investigational? (Y/N) | NSC Numbers must be provided if Agent is Investigational |
|------------|--|--|--|
| | | | NSC No. ¹ |
| | <input type="checkbox"/> yes <input type="checkbox"/> no | <input type="checkbox"/> yes <input type="checkbox"/> no | |
| | <input type="checkbox"/> yes <input type="checkbox"/> no | <input type="checkbox"/> yes <input type="checkbox"/> no | |
| | <input type="checkbox"/> yes <input type="checkbox"/> no | <input type="checkbox"/> yes <input type="checkbox"/> no | |
| | <input type="checkbox"/> yes <input type="checkbox"/> no | <input type="checkbox"/> yes <input type="checkbox"/> no | |
| | <input type="checkbox"/> yes <input type="checkbox"/> no | <input type="checkbox"/> yes <input type="checkbox"/> no | |

Please include as an attachment if additional space is required.

1.C Study Disease:

Phase 1 Studies (check one below):

- ☐ Solid Tumor (NOS)
☐ Hematologic Malignancy (NOS)
☐ Disease-Specific

Phase 2, 3 and Disease-Specific Phase 1 Studies (specify the Name and Code of the Study Disease below):

| Disease Name ¹ | Disease Code ¹ |
|---------------------------|---------------------------|
| | |
| | |
| | |

1.D Statistical Design (check all that apply):

Accrual Rate: _____ pts/month Total Expected Accrual: _____ min _____ max

- | | | | |
|---|--|--|---|
| <input type="checkbox"/> 1-Stage Design | <input type="checkbox"/> Cohort Study | <input type="checkbox"/> Historical Controls | <input type="checkbox"/> Single Blind |
| <input type="checkbox"/> 2-Stage Design | <input type="checkbox"/> Crossover | <input type="checkbox"/> Non-Randomized | <input type="checkbox"/> 2 x 2 Factorial Design |
| <input type="checkbox"/> 3-Stage Design | <input type="checkbox"/> Double Blind | <input type="checkbox"/> Pre-Randomized | <input type="checkbox"/> 4 x 4 Factorial Design |
| <input type="checkbox"/> Case Control | <input type="checkbox"/> Early Stopping Rule | <input type="checkbox"/> Randomized | |

1.E Cooperative Group and CCOP Research Bases Studies Only:

Protocol Chairperson: _____ Phone No.: _____

NCI Investigator No. ²: _____Is this an Intergroup Study? ☐yes ☐no If yes, list the expected Participants: _____Will this study be open to CCOP(s)? ☐yes ☐no**SECTION 2: EMBEDDED CORRELATIVE STUDIES****Section 2.a is required for all Treatment Protocols Section 2.b is required for all non-Group U01-funded protocols.**

An Embedded Correlative Study is a trial that is incorporated into a larger trial. The embedded study is included as a sub-trial or secondary end-point of the larger trial (i.e., obtaining pharmacokinetics during a treatment trial). The primary objective of collecting a description of embedded correlative studies is to document and recognize the important contributions to basic science that investigators are performing within a larger trial. This information may be utilized as a resource to improve collaboration between investigators and as a potential aid to improve funding of the NCI and its collaborators.

A brief description of all correlative studies embedded in this trial must be provided in the space below. The description of all correlative studies must have enough information to determine what the purpose of the study is. The same business rules that apply to writing the title of the primary trial should be employed. For example "pharmacokinetics" is insufficient. A more appropriate title would be "A pharmacokinetic study of taxol in combination with CTX in women with stage 3 metastatic breast cancer."

Does this study include an embedded correlative study(ies)? ☐yes ☐no If yes, complete sections 2.a and 2.b (if appropriate).**Section 2.a – required for all Treatment Protocols****Section 2.b – required for all non-Group U01-funded protocols**

| Description | Correlative Grant Number (if different from Treatment Grant Number) | Anticipated Number of Samples Analyzed | Estimated Cost/Sample Analyzed |
|-------------|--|--|--------------------------------|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |

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SECTION 3: GENDER AND MINORITY ACCRUAL ESTIMATES *Required for ALL phase 3 studies*³

In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the Department of Health and Human Services (HHS) requires that all Phase II and III trials must include accrual targets for males, females and minorities. The accrual targets should reflect the expected accrual over the life of the study.

The policy states that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rational and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The NCI suggests that the accrual targets be based on data from similar trials completed by your organization during the previous five years. It is hoped that the accrual targets will resemble the gender, racial and ethnic composition of the U.S. population as closely as possible.

Please see the **HHS Racial and Ethnic Categories** listed below for a complete description of racial and ethnic categories.

| | White, not of Hispanic Origin | Hispanic | Black, not of Hispanic Origin | Native Hawaiian or other Pacific Islander | Asian | American Indian or Alaskan Native | Other or Unknown | Total |
|----------|-------------------------------|----------|-------------------------------|---|-------|-----------------------------------|------------------|-------|
| Female: | | | | | | | | |
| Male: | | | | | | | | |
| Unknown: | | | | | | | | |
| Total: | | | | | | | | |

Enter actual estimates (*not percentages*).

HHS Racial and Ethnic Categories

White, not of Hispanic Origin: A Person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii or the pacific islands including Hawaii, the Philippine Islands and Samoa.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent. This area includes, for example, China, India, Japan, and Korea.

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

SECTION 4: COMMON DATA ELEMENTS (CDE) *Required for Cooperative Group Phase 3 Treatment Studies in the following diseases: Colorectal, Genitourinary, Breast, and Lung Cancer*³

Recommend that CDE changes/additions be submitted with original protocol submission. If necessary, CDE changes /additions may be submitted up to the time of protocol approval. Protocols will NOT be approved until this section is completed.

Are all terms utilized in the Case Report Forms from the CDE Dictionary (see <http://cii.nci.nih.gov/cde>)? ☐yes ☐no If no, please list each new/revised element (term) below:

| Term | New Addition | Revision of Existing Term/ Valid Values |
|------|--------------------------|--|
| | <input type="checkbox"/> | <input type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> |

Please include as an attachment if additional space is required.

SECTION 5: PERSON COMPLETING WORKSHEET

Provide the following information.

| | | |
|-------------------|------------------|-----------------------|
| Print Name | Phone No. | E-mail Address |
| Signature | Date | |

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